THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte GERE S. DI ZEREGA

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Appeal No. 1996-1934
Application 07/884,218

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ON BRIEF

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Before WILLIAM F. SMITH, SPIEGEL, and ADAMS, Administrative Patent Judges, ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-14, 16, 18, 19 and 22-31, which are all the claims pending in the application.

Claims 1, 22 and 23 are illustrative of the subject matter on appeal and are reproduced below:

1. A method for introduction of medicaments to and retaining said medicament in the peritoneal cavity of a mammal undergoing surgery which comprises providing to the peritoneal cavity a solution of a medicament to combat interperitoneal infection and a hyaluronic acid compound selected from hyaluronic acid and water-soluble salts thereof in a sterile isotonic, flowable, pharmaceutically acceptable media in which the hyaluronic acid compound is present in a concentration of at least about 0.4% by weight based on the weight of the solution, said solution having a viscosity at 25˚C of from about 500 to about 10,000 centipoise, said hyaluronic acid compound serving to retain said medicament in the peritoneal cavity.

22. A method for combating infections of the peritoneal cavity which comprises providing to the peritoneal cavity of a mammal undergoing surgery, a solution of a medicament and an hyaluronic acid compound selected from hyaluronic acid and water-soluble salts thereof in a sterile, isotonic, flowable pharmaceutically acceptable media in which the hyaluronic acid compound is present in a concentration of at least about 0.4% by weight based on the weight of the solution, said solution having a viscosity at 25˚C of from about 500 to about 10,000 centipoise, said hyaluronic acid compound acting to retain the inroduced medicament in the peritoneal cavity, the amount of solution applied being in an amount sufficient to at least coat traumatized tissue and up to an amount sufficient to coat the peritoneal cavity, said solution being applied to the peritoneal cavity during the period from beginning of surgery up to closure at conclusion of surgery.

23. A method as claimed in claim 22 in which the solution is applied as a single application at closing of the peritoneal cavity at the end of the operative procedure.

The references relied upon by the examiner are:

Della Valle et al. (Della Valle)	4,736,024	Apr. 5, 1988
Goldberg et al. (Goldberg)	5,080,893	Jan. 14, 1992

GROUND OF REJECTION

Claims 1-14, 16, 18, 19 and 22-31 are rejected under 35 U.S.C. § 103 over Goldberg in combination with Della Valle.

We affirm the rejection of claims 1-14, 16, 18, 19, 22 and 24-31 and reverse the rejection of claim 23.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, and to the respective positions articulated by the appellant and the examiner. We make reference to the Examiner's Answer (Paper No. 32, mailed February 8, 1995), for the examiner's reasoning in support of the rejection. We further reference appellant's Brief as amended (Paper No. 31, received July 29, 1994), and appellant's Reply Brief (Paper No. 34, received April 17, 1995) for the appellant's arguments in favor of patentability.

CLAIM GROUPING:

At page 5 of the Brief, appellant states that the claims do not stand or fall together reciting 6 groupings. However, appellant merely points out the differences in what the claims cover. Appellant does not argue the merits of any particular claim apart from the others. See, Brief, pages 13-14. Therefore, with the exception of claim 23, which will be addressed separately below, all claims, stand or fall together with representative independent claim 1. In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

THE REJECTIONS UNDER 35 U.S.C. § 103:

Claims 1-14, 16, 18, 19, 22 and 24-31:

At page 4 of the Answer, the examiner states:

> Goldberg et al disclose introduction of hyaluronic acid into peritoneal cavity (see, for example, column 5, lines 63-68 and column 6, lines 13-15) but do not disclose introduction of a combination of hyaluronic acid and a medicament into peritoneal cavity. However, since della Valle et al. disclose hyaluronic acid to be a conventional carrier for various medicaments, including antibiotic clindomycin, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to introduce into peritoneal cavity a solution of hyaluronic acid and a medicament in order to prevent surgical adhesions and to combat intraperitoneal infection.

Appellant argues at page 10 of the Brief that in order:

> To determine whether the Examiner's position has merit one must determine how far the applied art went and the standards for surgical procedure to determine whether the surgeon would leave a solution of hyaluronic acid and a medicament in the peritoneal cavity following surgery to combat bacterial infections on closure.

Appellant emphasizes the idea of leaving a solution of hyaluronic acid and a medicament in the peritoneal cavity, at page 12 of the Brief, citing the di Zerega Declaration (Paper No.13, received September 28, 1992), and stating "standard operating procedure was to remove all adjuvant substances and aspirate all excess irrigant at closure." Appellant further emphasized this position in the Reply Brief, bridging paragraph of pages 3-4, "the specification makes clear that the hyaluronic

acid is used to retain the medicament in the peritoneal cavity at closure, a result inconsistent with removal of the solution prior to closure."

Page 3 of the specification states "[i]n the practice of the invention, the hyaluronic acid solution and the medicament is applied topically to the peritoneal cavity . . .." Page 13 of the specification states "[t]he HA is administered to the site of surgical trauma within the peritoneal cavity topically. Such topical administration can be by lavage, dripping on the site from a syringe or other suitable container/applicator, by catheter administration, or the like."

The specification refers to topical administration, therefore, contrary to appellant's argument we see nothing inconsistent with the specification in removing excess solution from a topically administered composition prior to closing. In addition, as the examiner points out at page 5 of the Answer, "instant claims do not exclude removing hyaluronic acid solution prior to closure of peritoneal cavity." Therefore, appellant's argument concerning "leaving a solution of hyaluronic acid and medicament in the peritoneal cavity" is not persuasive.

Appellant argues that Della Valle fails to include the peritoneum in the list of the various areas of the body upon which topical treatment using a solution of hyaluronic acid and a medicament can be made. See, Reply Brief, page 2. It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references. Pro-Mold and Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed.

Cir. 1996). In this case, the examiner provides a reason to use hyaluronic acid, a conventional carrier for various medicaments, in the method of Goldberg. As explained by the examiner at page 4 of the Answer:

> [S]ince della Valle et al disclose hyaluronic acid to be a conventional carrier for various medicaments, including antibiotic clindomycin, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to introduce into peritoneal cavity a solution of hyaluronic acid and a medicament in order to prevent surgical adhesions and to combat intraperitoneal infection.

Therefore, appellant's position regarding the motivation to combine Della Valle with Goldberg is not persuasive.

At page 13 of the Brief, appellant argues that Table 1 and Table 2, see specification pages 9 and 10, establish that when an antibiotic is combined with hyaluronic acid, unexpected and synergistic results are obtained. However, "synergism is one factor to be considered in the ultimate determination of obviousness of the composition . . . we attribute no magic status to synergism per se since it may be expected or unexpected." In re Huellmantel, 324 F.2d 998, 1003, 139 USPQ 496, 500 (CCPA 1963). On the record before us, we see nothing "unexpected" in appellant's synergism. Nothing in the record shows that similar synergism would not be obtained by the combination of Della Valle with Goldberg. We note of interest Table 1, column 26 of Della Valle, which demonstrates that the combination of hyaluronic acid and antibiotic was better than antibiotic alone. Therefore, we are not convinced that appellant's synergism is unexpected.

Accordingly, we affirm the rejection of claims 1-14, 16, 18, 19, 22 and 24-31 under 35 U.S.C. § 103.

Claim 23:

At page 2 of the Reply Brief appellant states "Goldberg et al. make clear in Example 4 that irrigation with the same (HA) solution at conclusion of surgery prior to closure resulted in a detrimental occurrence of 80% adhesions of significance in test rats." Claim 23 requires a single application of the solution at closing of the peritoneal cavity at the end of the operative procedure. The examiner did not specifically address this issue.

Goldberg distinguishes between the "convention or prior art methods" which administer hyaluronic acid solutions at the end of surgery prior to closing and Goldberg's invention in which tissues are coated prior to surgical manipulation. See, e.g., Goldberg, Example 4, column 8. At column 8, line 65 - to – column 9, line 1, Goldberg concludes, "there is no observed benefit to the use of the aqueous polymer solutions of this invention if used according to conventional or prior art methods", for example a single application of solution at closing. Therefore, Goldberg teaches away from a single application of a

hyaluronic acid solution at closing of the peritoneal cavity as required by claim 23.

Accordingly, we reverse the rejection of claim 23 under 35 U.S.C. § 103.

AFFIRMED-IN-PART

WILLIAM F. SMITH Administrative Patent Judge	)
CAROL A. SPIEGEL Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES
DONALD E. ADAMS Administrative Patent Judge	)

DEA/kis
CHRISTIE, PARKER & HALE
P. O. Box 7068
Pasadena, CA 91109-7068